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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,684

01/28/2004

Nabil L. Muhanna

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99334

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/766,684	<b>Applicant(s)</b> MUHANNA ET AL.	
	<b>Examiner</b> Bruce E. Snow	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19 and 21-42 is/are pending in the application.
- 4a) Of the above claim(s) 33 and 37-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 21-32, 34-36, 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

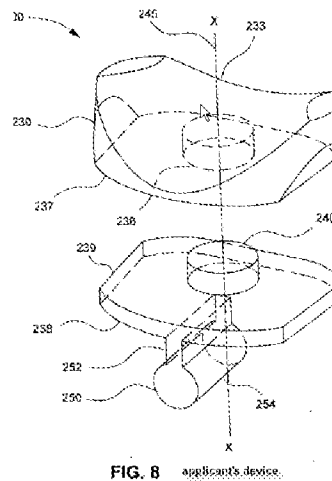
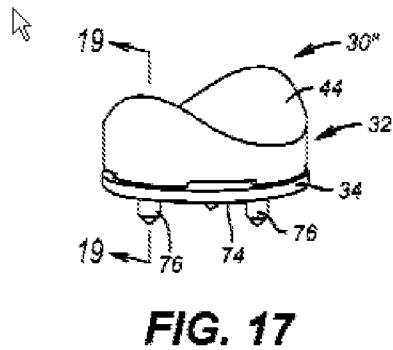
- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Response to Arguments***

Applicant's arguments filed September 09, 2010 have been fully considered. Regarding the nonstatutory double patenting rejection, the Office action dated November 19, 2007 withdrew claims 37-41 directed to a "method of providing". U.S. serial No. 11/648,384 is again directed to the device and not the withdrawn "method of providing". The double patenting rejection is correctly applied.

Regarding the rejections using Burkinshaw (6,602,292), again, it is the Examiner's position that the device of Burkinshaw is sized and configured and fully capable of being used in the disc. MPEP 2114 teaches: *A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.* Merely labeling the device a intervertebral disc does not imply any specific structure not taught by Burkinshaw. Figure 17 below shows the device of Burkinshaw next to applicant's rotatable embodiment.

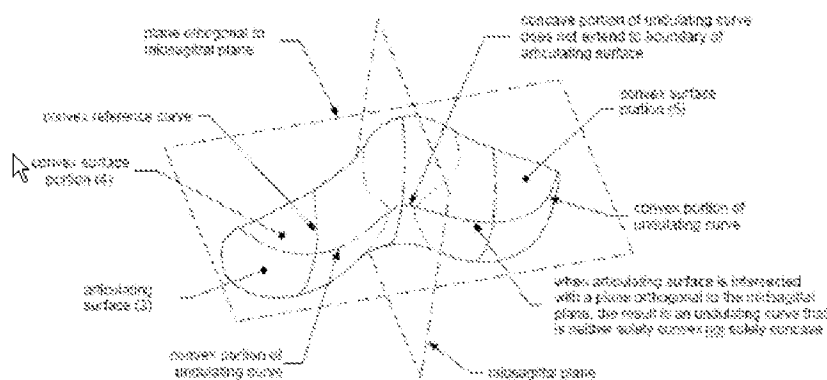


It is the examiner's unyielding position is that the device of Burkinshaw is sized and shaped to function as claimed.

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Shelokov (6,039,763), applicant suggest the surface is as shown:

Application No. 10/766,684  
Response to Office Action mailed June 12, 2009

Attorney Docket No.: 126913-1003  
Customer No. 32914



The device of Shelokov along the midsagittal plane is solely convex; applicant notes col. 5, line 66 to col. 6, line 3, which does not describe the midsagittal plane.

The term "boundaries" is not limited to the outer peripheral boundary of the articulating surface. Giving the term its broadest reasonable interpretation, the

boundaries can be drawn at or approximate planes P4 and P5 which is a natural boundary defined by the apices.

Regarding the Linscheid et al rejection, it is the examiner's position that the device of Klawitter is sized and configured and fully capable of being used in the disc. MPEP 2114 teaches: *A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.* Additionally, the prosthetic is fully capable of being implanted into an intervertebral disc of some type of animal. Applicant claiming the joint as a disc body does not require any additional structure not taught by Linscheid et al.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 21-32, 34-36, 42 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19-36 of copending Application No. 11/648,384. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other claiming the same device comprising:

A prosthetic disc comprising:

a disc body, having a first surface that is a concave-convex articulating surface and a second surface as a base adapted for fixation to a first bone surface.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

***Claim Rejections - 35 USC § 103***

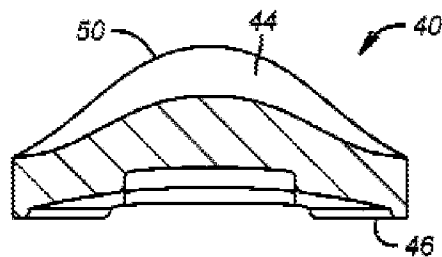
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 21-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burkinshaw (6,602,292).

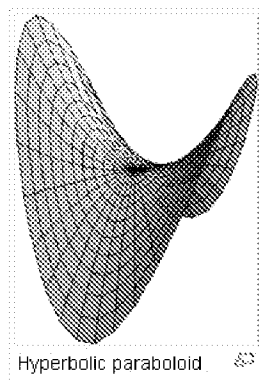
Burkinshaw teaches a prosthetic disc comprising:

**First interpretation:**



**FIG. 4**

a disc body 40 having a first surface 44 that is a concave-convex articulating surface and a second surface 46 as a base **adapted** for fixation to a first bone surface, wherein the concave-convex articulating surface is hyperbolic paraboloid (see 4:8) meeting all claim limitations.

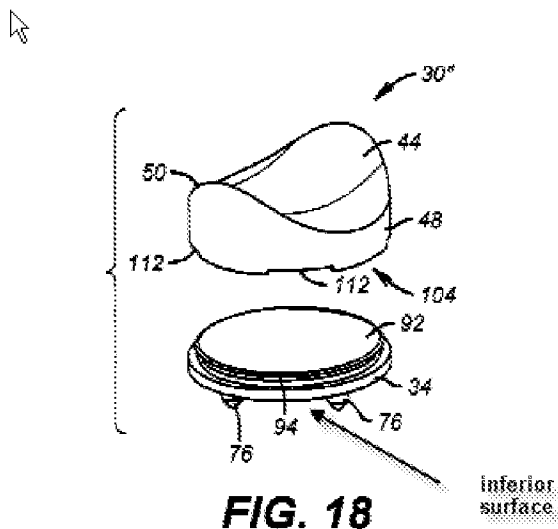




Regarding claim 1 requiring “a solely convex reference curve having a substantially uniform radius”, it is the examiner's position that that generic teaching of a hyperbolic paraboloid by Burkinshaw meets this limitation despite Burkinshaw teaching in figure 4 what appears to be convex side portions along the midsagittal plane.

Regarding the base surface 46, note that the non-flat surface configuration including elements such as 52 and 54 shown in figure 10, would act as an anchor point for bone cement fixation. Therefore, the articulating surface and second surface are relatively fixed.

**Second interpretation:** a disc body 30 having a superior surface 44 that is a concave-convex articulating surface meeting all claimed limitations and a second inferior surface adapted for fixation to a vertebral bone surface, wherein the concave-convex articulating surface is hyperbolic paraboloid (see 4:8).



It is the Examiner's position that the two components (32, 34) of Burkinshaw are rotatably coupled but snap together preventing separation which is interpreted as being

"fixed" together. Therefore, the articulating surface is fixed relative to the inferior surface. The Examiner notes that Burkinshaw teaches the advantages of having said two components rotatably/translationally coupled over the art. It is within the scope of the teachings that the components could be non-rotatably and non-translationally coupled (inherent) or at a minimum, obvious to try with predictable (rejection under 35 U.S.C. 103(a)).

It is the Examiner's position that the device of Burkinshaw is sized and configured and fully capable of being used in the disc. MPEP 2114 teaches: *A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.*

Claim 24, it is possibly that the disc body was made of separate components connected together. This claim has been interpreted as a product by process limitation which fails to differentiate. The second interpretation uses a two component configuration.

Claims 26-28, see 5:48 et seq.

Claim 29 is functional language only.

Claim 30, fully capable of.

Claim 31, regarding "wherein the concave reference curve extends from a first end of the articulating surface to a second end of the articulating surface", it is the examiner's position that the "concave reference curve" can include other shapes. Additionally, the articulating surface can be interpreted as ending at planes P4 and P5.

Claim 34 is not positively claiming the second body.

Regarding claim 42, "has a hyperbolic paraboloid shape" is interpreted as being broader and does not limit explicitly to being a hyperbolic paraboloid.

Claims 19, 21-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as anticipated by Shelokov (6,039,763).

Shelokov teaches a prosthetic disc comprising:  
a first and second disc bodies 1, 10 having complimentary saddle shaped articulating surfaces each surface being one of concave and convex in a first plane and the other of concave and convex in a perpendicular plane to the first. The articulating surface 3, at the midsagittal plane  $P_1$ ,  $X_1$ , is *"a solely convex reference curve having a substantially uniform radius"*.

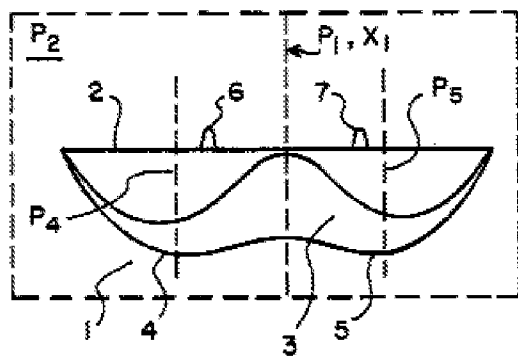


FIG. 1b

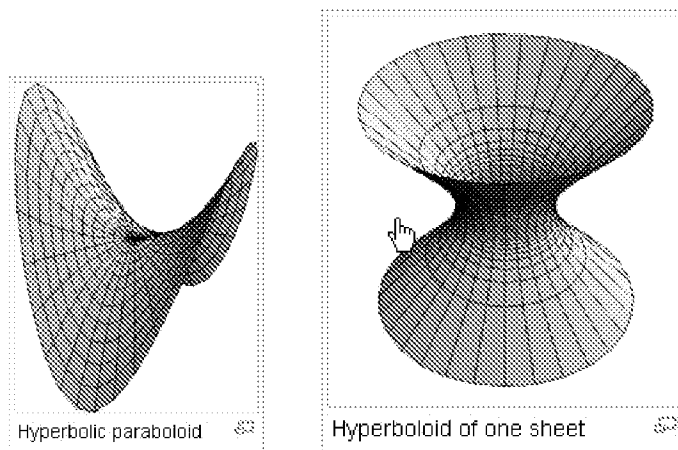
Plane  $P_2$ , (figure 1b) which is orthogonal to the midsagittal plane, is concave between planes  $P_4$  and  $P_5$ . This configuration fulfills the language, "and wherein concave reference curves are formed when the single articulating surface is intersected with planes orthogonal to the midsagittal plane". It is the examiner's position that planes

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P4 and P5 are the ends of the boundaries of the concave portion of the single articulating surface. "Boundaries" is not limited to the outer peripheral boundary of the articulating surface. Additionally, it is the examiner's position that the "concave reference curve" can include other shapes and is not limited to being solely concave.

Shelokov further teaches, "*the articulating surfaces (3,12) can be regularly or irregularly shaped as at least partially complementary portions of.. paraboloids (6:51 et seq.).*"

Wikipedia teaches, "*In mathematics, a **paraboloid** is a quadric surface of special kind. There are two kinds of paraboloids: **elliptic** and **hyperbolic**.*"



Referring to the first and second disc bodies of Shelokov, the articulating surface 3, 12 (between lines P4 and P5) are clearly a hyperbolic paraboloid shape and not an elliptic paraboloid. As quoted above, the surfaces can be regular shape paraboloids which are hyperbolic as taught from the drawings. Hyperbolic paraboloids are inherently concave-convex. Shelokov teaches that the plane P1 is convex; see 5:66-6:3.

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Additionally, Shelokov teaches the articulating surfaces can be a hyperboloid which meets all claims. Same for claim 35.

Regarding claim 19, a midsagittal plane is solely convex.

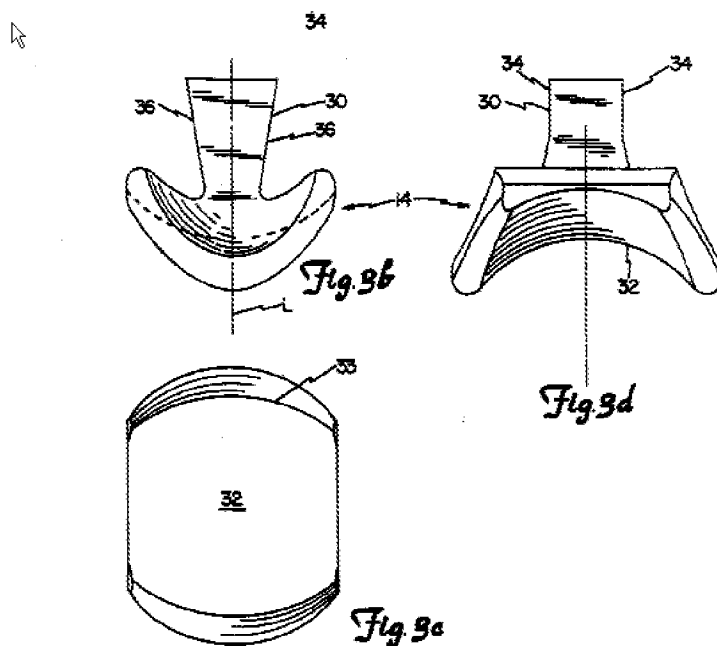
Note that the second surface 2 of body 1 is fixed relative to the articulating surface 3.

Regarding claim 42, "the superior articulating surface has a single shape characterized as a hyperbolic paraboloid", the single shape of portions 3, 12 is a hyperbolic paraboloid.

Regarding claims 24-27, see at least 9:47 et seq. teaching at least coatings.

Claims 19, 21-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Linscheid et al (5,405,400) as evidenced by Klawitter (5,645,605) and Lunborg (6,342,076).

Linscheid et al teaches a joint prosthetic comprising a disc body 14 having a first articulating surface 32 which is a hyperbolic paraboloid shape (see 3:56) and second surface which is relatively fixed. Clearly the midsagittal plane is solely convex as shown in figure 3b. The articulating surface is concave in a plane orthogonal to the midsagittal plane as shown in figure 3d.



It is the Examiner's position that the device of is sized and configured and fully capable of being used in the disc. MPEP 2114 teaches: *A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.* Additionally, the prosthetic is

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fully capable of being implanted into a intervertebral disc of some type of animal.

Applicant claiming a “disc body” does not define or add any additional structural differences over the body 14 of Linscheid et al.

In the alternative, under 35 U.S.C. 103(a): If the body 14 of Linscheid et al is not interpreted as a disc body.

The abstract of Linscheid et al describes the device as a “joint prosthesis [is] provided for replacing a joint between two bone”. It is the examiner’s interpretation that Linscheid et al contemplated this device could be used for various joints within the body.

Klawitter also teaches a concave-convex thumb joint prosthesis and states one skilled in the art at the time of the invention would known to use/try the device in other joints. Klawitter states, “*for example, the articulated prosthetic joint described herein is also contemplated for the replacement of human anatomical joints other than the CMC joint of the thumb* (column 7, lines 7-10)”.

Finally, Lundborg also describes what one skilled in the prosthetic joint art would know at the time of the invention (column 4, lines 47 et seq.): “*The invention can also be used.. as an artificial joint between the first metacarpal bone and the trapezoid bone (same as Linscheid et al and Lundborg). The invention can also be used as bone replacement for intervertebral discs or individual vertebrae in the spinal column.*” And further teaches: “*In the spinal column, there may be a need of replacing intervertebral discs or individual discs in various diseases. Also in this case, a prosthetic device for joints having a suitable size and design may constitute a satisfactory replacement material.*”

It is the examiner's position that one skilled in the art at the time of the invention would have tried a prosthetic joint configuration at various anatomical joints as evidenced above. Also, it would have also been obvious to have tried said configurations as a thumb joint or as a disc as evidenced above. Therefore, it would have been obvious to one skilled in the art to have tried/modified the prosthetic joint of Linscheid et al as an intervertebral disc to replace a diseased disc.

All other limitations are self-evident.

### ***Conclusion***

This is a RCE of applicant's earlier Application No. 10,766,684. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruce E Snow/

Primary Examiner, Art Unit 3738